

REMARKS**I. Claim status**

Upon entry of the above amendments, claims 1, 4, 5, 6, 7, 12, 13, 19, 20, 80, 84, 85, 87, 89, 91, 92, 94 and 95 will be pending in this application. Claims 10, 15, 17, 88, 90 and 93 have been canceled without prejudice to their presentation in a continuing application. Pending claims 1, 13, 87, 89 and 94 have been amended, as shown in the Response filed on October 27, 2003 (but were not entered per the Advisory Action dated November 13, 2003). Support for amended claims 1, 13, 87, 89 and 94 can be found throughout the specification and in the original claims. No new matter has been added.

The amended claims were not entered because amended claim 13 allegedly raises new grounds of rejection under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner states that there is no antecedent basis for "said penetration enhancer" in claim 13. The phrase "said penetration enhancer" of claim 13 is now deleted. Thus, the Applicants have overcome the rejection under 35 U.S.C. § 112, second paragraph.

Accordingly, the Applicants respectfully request the Examiner to reconsider pending claims 1, 4, 5, 6, 7, 12, 13, 19, 20, 80, 84, 85, 87, 89, 91, 92, 94 and 95.

II. The claims are novel*The Kawai reference*

Claims 1, 5, 6, 7, 10, 17, 19, 20 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by unexamined Japanese Patent Application No. 7-330614 (hereinafter "Kawai"). Applicant respectfully traverses the rejection because Kawai fails to teach or suggest all the elements of the present invention. *Glaxo v. Novopharm, Ltd.*, 334 U.S.P.Q.2d 1565 (Fed. Cir. 1995). For example, Kawai fails to disclose, teach or suggest a composition in "dosage form." As is identified by the specification of the present application, a "dosage form" is one in which the components of the composition are "uniformly" distributed. See page 58, lines 4-14, of the specification. Kawai is

devoid of any information regarding a composition being in a dosage form. Further, Kawai fails to disclose or teach the inclusion of "bile salts" in the composition.

Because Kawai fails to teach or suggest every element of the invention, the claims are not anticipated. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 102(b).

The Hnatowich Reference

Claims 1, 4-7, 15 and 84 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Pat. No. 5,980,861 (hereinafter "Hnatowich"). Applicant respectfully traverses the rejection because Hnatowich fails to disclose, teach or suggest every element of the claimed invention. For example, Hnatowich fails to disclose, teach or suggest the inclusion of "bile salts" in the composition. Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 102(e).

The Nielson Reference

Claims 87-96 stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by WO 97/13528 (hereinafter "Nielson"). Applicant traverses the rejection and respectfully points out that Nielson cannot qualify as a reference under section 102(b) because the international publication date of Nielson (April 17, 1997) is less than one year prior to the priority date of the present application (July 1, 1997).

Applicant further asserts that Nielson cannot anticipate Claims 87-96 under 35 U.S.C. § 102(a) either because Nielson fails to disclose, teach or suggest every element of the claimed invention. For example, Nielson fails to disclose, teach or suggest the inclusion of "bile salts" in the composition.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 102 (a) and (b).

III. The claims are not obvious

Claims 12, 13, 80, and 85 stand rejected under 35 U.S.C. § 103 as allegedly being obvious over Kawai in view of New, Bennett and Nielson. Applicant respectfully traverses the rejection because the Office Action has failed to make a *prima facie* case of obviousness.

In establishing a *prima facie* case of obviousness under 35 U.S.C. §103, it is incumbent upon the Office to provide a **reason** why one of ordinary skill in the art would have been led to modify a prior art reference or to combine reference teachings to arrive at the claimed invention. *Ex parte Clapp*, 227 U.S.P.Q. 972 (Bd. Pat. App. Int. 1985). To this end, the requisite motivation must stem from some teaching, suggestion or inference in the prior art as a whole or from the knowledge generally available to one of ordinary skill in the art and not from appellants' disclosure, see for example, *Uniroyal Inc. v. Rudkin-Wiley Corp.*, 5 U.S.P.Q.2d 1434 (Fed. Cir. 1988); and *Ex parte Nesbit*, 25 U.S.P.Q.2d 1817, 1819 (Bd. Pat. App. Int. 1992). In this respect, the following quotation from *Ex parte Levengood*, 28 U.S.P.Q.2d 1300, 1302 (Pat. Off. Bd. App. 1993), is noteworthy:

Our reviewing courts have often advised the Patent and Trademark Office that it can satisfy the burden of establishing a *prima facie* case of obviousness only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that "would lead" that individual "to combine the relevant teachings of the references." ... Accordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing evidence of the motivating force that would **impel** one skilled in the art to do what the patent applicant has done.

(citations omitted; emphasis added).

The claims being rejected under 35 U.S.C. § 103 recite, *inter alia*, a composition comprising a bile salt. The Office Action alleges that "one of ordinary skill in the art would have been motivated to modify the compositions of Kawai [*sic*] with the bile salts

of New" to arrive at the present invention. Contrary to the allegation, one of ordinary skill would not have been motivated, or **impelled**, to combine Kawai and New to arrive at the claimed invention.

Kawai reports a **liquid** formulation comprising a fat emulsion and a transducing gene. However, Kawai does not disclose, teach or suggest a composition comprising a bile salt.

New fails to provide for the deficiency of not having bile salts in the Kawai composition. New reports that the low therapeutic index of bile salts in the oral delivery of a drug may be countered by an appropriate buffer. Further, one of ordinary skill in the art would recognize that the bile salt/buffer combination reported by New is intended for **solid** dosage form. One of ordinary skill in the art would not be impelled to combine the liquid formulation of Kawai with the bile salts/buffer composition of New because, for example, the bile salts/buffer combination of New that is intended for a solid dosage form would be **poorly suited** for the liquid formulation of Kawai. Since one of ordinary skill in the art would not be impelled, or motivated, to combine Kawai and New to arrive at the present invention, the present invention is not obvious.

Bennett and Nielson, independently or combined, also fail to provide for the deficiency of Kawai because neither reference discloses the use of bile salts in a formulation.

Accordingly, Applicant respectfully requests reconsideration and withdrawal of the rejection of the claims under 35 U.S.C. § 103.

IV. Conclusion

In view of the foregoing, Applicant submits that the pending claims are in condition for allowance, and an early Office Action to that effect is earnestly solicited.

Respectfully submitted,



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